IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MOUSSA KOUYATE, individually and on behalf of all others similarly situated,

Plaintiff,

v.

THE HARVARD DRUG GROUP L.L.C. d/b/a RUGBY LABORATORIES,

Defendants.

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

Case No. 1:24-cv-06223-GHW-SDA

ORAL ARGUMENT REQUESTED

MEMORANDUM OF LAW IN SUPPORT OF THE HARVARD DRUG GROUP, L.L.C. D/B/A RUGBY LABORATORIES' MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTRODUCTION

Plaintiff Moussa Kouyate ("plaintiff") brings this putative class action against The Harvard Drug Group, L.L.C., d/b/a Rugby Laboratories ("THDG") seeking restitution, actual and statutory damages, and attorneys' fees related to his and putative class members' alleged purchase of THDG's Benzoyl Peroxide Wash USP 10% and other acne medication products containing benzoyl peroxide ("BPO Products"). He premises his claims on: (1) a Citizen Petition submitted to the Food and Drug Administration ("FDA") by "independent" laboratory Valisure, LLC ("Valisure"), which purportedly found that certain acne medication products containing benzoyl peroxide contained varying levels of the carcinogen benzene after being heated to extreme temperatures over several days, and (2) unspecified and undisclosed "independent testing" performed by plaintiff on THDG's BPO Product at room temperature, which purportedly reflected "benzene at levels that . . . render the Product dangerous to human health and illegal to sell in the United States[.]" Complaint ("Compl.") ¶¶ 17-20. At bottom, plaintiff's theory is that "all lots of Defendant's BPO Products contain and/or systematically degrade to form benzene" *Id.* ¶ 17.

Plaintiff's claims for (1) violation of the New York False Advertising Act, New York Gen. Bus. Law § 350 ("FAA"); (2) fraud/misrepresentation; and (3) negligence per se should be dismissed for three reasons:

First, plaintiff's claims are expressly preempted by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA") and supporting regulations, which govern the sale, labeling and marketing of THDG's BPO Products. Plaintiff seeks to override the FDA's approved ingredient formulation and labeling of acne medications containing benzoyl peroxide by asking THDG to list "benzene" on its labels or include warnings that benzoyl peroxide can degrade to form benzene. The relief requested would impose obligations "in addition to or different from"

FDA-promulgated statutes and rules. This is prohibited by federal law's mandate of national uniformity for nonprescription drugs. 21 U.S.C. § 379r. A California federal court has already rejected plaintiff's theory by dismissing similar suits against other manufacturers whose BPO products were tested by Valisure because the claims are squarely preempted. *See Howard v. Alchemee, LLC*, Nos. 2:24-cv-01834, 2:24-cv-01876, 2:24-cv-01878, 2024 WL 4272931 (C.D. Cal. Sept. 19, 2024) (granting motions to dismiss in three cases). The Court should do the same here.

Second, alternatively, the Court should dismiss or stay this case because the FDA has primary jurisdiction to decide whether THDG's BPO Products are appropriately labeled, contain unacceptable levels of benzene, or should be recalled. Valisure has already asked the FDA to answer these issues and grant this relief in its Citizen Petition submitted to the agency last March, and the agency is engaging with Valisure in response to these issues.

Third, plaintiff fails state a claim for any of his state law causes of action because he has not: (A) plausibly alleged that the BPO Products' labeling or advertising is misleading to a reasonable consumer or identified any actionable misrepresentations or omissions under the FAA, (B) pleaded his fraud claim with particularity or alleged any facts from which the Court could infer that THDG acted with fraudulent intent, or (C) plausibly alleged that THDG's BPO products were misbranded or adulterated in violation of New York law to support a negligence per se claim.

BACKGROUND

I. FDA Approval and Guidance for Acne Medications Containing Benzoyl Peroxide

The FDA regulates acne medications containing benzoyl peroxide, including THDG's BPO Products, through a "monograph," consisting of regulations setting forth approved doses, formulations, and labeling for the sale and marketing of over the counter ("OTC") drugs. *See* 21

C.F.R. § 330.10, *et seq*. When an OTC medication is approved through the FDA's monograph process, as it was here, an advisory panel of qualified experts assigned by the FDA has reviewed extensive data and expert recommendations regarding the OTC drug and concluded that when sold and marketed under the monograph conditions, the OTC drug "is generally recognized as safe and effective and is not misbranded." 21 C.F.R. §§ 330.10(a)(1), (3); 330.10(a)(7)-(9). Through the monograph process, the FDA expressly approves OTC drugs' active ingredients, and "provides the conditions under which each active ingredient is [generally recognized as safe and effective (GRAS/E")]." *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013). If an ingredient is not considered GRAS/E, the drug cannot contain that ingredient. *See id.* And if an OTC drug is not sold, labeled, and marketed in accordance with its monograph, it is subject to regulatory action. *See* 21 C.F.R. § 330.10(a)(12).

Since 2010, benzoyl peroxide has been an authorized active ingredient under the FDA monograph for acne medications. *See* 21 C.F.R. §§ 333.350(c)(4), (d)(2), 330.10(a); FDA's Classification of Benzoyl Peroxide as Safe and Effective, 75 Fed. Reg. 9767, 9768 (Mar. 4, 2010). In other words, the FDA recognizes benzoyl peroxide as a safe and effective active ingredient when sold in concentrations of 2.5-10%. *See* 21 C.F.R. §§ 333.301, *et seq.* and 333.350, *et seq.* The FDA made this determination based on decades of research including studies on the carcinogenetic qualities of benzoyl peroxide. *See* FDA's Classification of Benzoyl Peroxide as Safe and Effective, 75 Fed. Reg. at 9770 (concluding that benzoyl peroxide is not a carcinogen). An acne medication containing benzoyl peroxide that complies with the specific warning and labeling requirements set forth in the FDA's monograph is thus "generally recognized as safe and effective and not misbranded." 21 C.F.R. §333.301; *see* 21 C.F.R. § 330.10. Although the possibility that benzoyl peroxide can degrade to form benzene under certain conditions has been

"well known" in the scientific literature since as early and 1936 (*see* Compl. ¶ 63), the FDA does not require acne medications containing benzoyl peroxide to include warnings that benzoyl peroxide contains or may degrade to form benzene. In December of 2023, the FDA issued non-binding guidance[1] which reminded drug manufacturers not to use benzene in their manufacturing processes and not to release drug product batches containing more than 2 parts per million (ppm) of benzene, in accordance with International Conference on Harmonization ("ICH") recommendations.[2] *See* Compl. ¶¶ 31, 48.

II. THDG's BPO Products

THDG, under the brand Rugby Laboratories®, distributes and sells OTC medication used to treat acne, including the Benzoyl Peroxide Wash USP 10% that plaintiff allegedly purchased, as well as other acne medications containing benzoyl peroxide. *See* Compl. ¶¶ 16, 78. In accordance with the FDA monograph, THDG's BPO Product labels list benzoyl peroxide as an active ingredient and directs users to store the product at room temperature. *See id.* ¶¶ 45, 77. THDG's BPO Products' labels comply with all requirements for OTC drug product labeling set forth by the FDA, *see* 21 C.F.R. § 201.66, and plaintiff does not allege otherwise. Rather, plaintiff's issue with THDG's BPO Products' labeling is that THDG "fail[ed] to disclose on the . . . labeling

[1] Defendant's Request for Judicial Notice ("RJN"), Ex. A (U.S. Food & Drug Administration, *FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs* (Dec. 27, 2023), https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs). Plaintiff refers to, and incorporates by reference, this document and others throughout his Complaint (*see, e.g.*, Compl. at 5 nn.1-2, 8 n.17, 12 n.39), making it appropriate for the Court to rely on these documents for purposes of this motion to dismiss. *See Phillips v. City of New York*, No. 21-CV-08149, 2024 WL 4307923, at *2 (S.D.N.Y. Sept. 26, 2024) (quoting *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47 (2d Cir. 1991)). In the alternative, THDG has filed a Request for Judicial Notice regarding these documents concurrently with its Motion to Dismiss.

[2] *See* RJN, Ex. B (U.S. Food & Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, *QC3 — Tables and List Guidance for Industry*, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (rev. 4 Aug. 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q3c-tables-and-list-rev-4 ("ICH Q3C Guidance")).

or anywhere in its marketing that the BPO Product contains benzene or can degrade to form benzene." Compl. ¶ 45.

III. Valisure's Study and Citizen Petition to FDA

Valisure is a self-proclaimed "independent" laboratory that has submitted several petitions to the FDA based on reports of finding benzene in products such as sunscreen and dry shampoo.[3] In March of 2024, Valisure published a study claiming to have detected benzene in certain acne mediations. Compl. ¶ 43.[4] Valisure's study did not purport to test THDG's BPO Products. Rather, the study claims that after heating up unspecified batches of BPO products to temperatures ranging from 98.6 degrees to 158 degrees Fahrenheit over multiple days, the benzoyl peroxide in some tested products degraded to form benzene in varying levels above 2 ppm. *See* RJN, Ex. C. Valisure also submitted a Citizen Petition to the FDA in which it purports to have detected varying levels of benzene in certain of THDG (and others) BPO products.[5] *See* Compl. ¶¶ 17-19, 37-43. Through its petition, Valisure asked the FDA to, among other things, request a recall and suspension of sale of all products containing benzoyl peroxide, find that these drugs' propensity to form benzene renders them misbranded, conduct examinations of the products' manufacturing processes, and review and update the current ICH Q3C Guidance on what constitutes "safe" levels of benzene. *See* Compl. ¶ 39; Valisure Citizen Petition at p. 4. Neither the published Valisure study nor the Citizen Petition include findings that THDG's BPO Products contained more than 2 ppm of

[3] These reports have been met with criticism. *See, e.g.*, *In re Zantac Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1091-94 (S.D. Fla. 2022) (describing Valisure's methodology as "flawed" and noting FDA's criticism of same); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 20-MD-2924, 2022 WL 1591128, at *3 (S.D. Fla. May 19, 2022) (noting "evidence . . . that Valisure was coordinating its efforts with attorneys").

[4] RJN, Ex. C (Kaury Kucera, et al., Research Letter, *Benzoyl Peroxide Drug Products Form Benzene*, Environmental Health Perspectives, Vol. 132(3), at 037702-1-037702-3 (Mar. 14, 2024), https://doi.org/10.1289/EHP13984).

[5] *See* RJN, Ex. D (Letter from David Light, President Valisure LLC, et al. to Division of Dockets Management, U.S. Food & Drug Administration, Valisure Citizen Petition on Benzene in Benzoyl Peroxide Drug Products (Mar. 5, 2024), https://www.regulations.gov/document/FDA-2024-P-1130-0001 ("Valisure Citizen Petition")).

benzene when tested directly off-the-shelf or that any BPO products formed benzene during the manufacturing process.

On June 3, 2024, the FDA met with Valisure to discuss its petition (and three others involving the potential for benzene contamination in hand sanitizer, sunscreen, and antiperspirant products), in part "to hear about Valisure's business and future plans and to share information about appropriate analytical testing approaches for the work that Valisure does."[6] The FDA is still considering Valisure's benzoyl peroxide petition given the "complex issues requiring extensive review and analysis by Agency officials[.]"[7]

IV. Plaintiff's Allegations

Plaintiff claims that he purchased THDG's BPO Product for $15 from a pharmacy in the Bronx, N.Y. "in approximately 2024" and read and understood the product's "accompanying labels and disclosures . . . as representations and warranties . . . that the BPO Product was properly manufactured, free from defects, safe for its intended use, and not adulterated or misbranded." Compl. ¶ 8. At some point after buying the product, but before suing THDG, he alleges that he "subjected the BPO Product to testing by an independent laboratory" at room temperature and that "[t]he product was found to contain excessive levels of benzene—in amounts well above the maximum set by the FDA for drug product sold in the United States[.]" *Id.* ¶¶ 8, 19. Plaintiff alleges nothing else about this testing, including the conditions in which his product was stored

[6] *See* RJN, Ex. E (Minutes of Meeting with Valisure, LLC, Docket No. FDA-2024-P-1130 (June 3, 2024), https://www.regulations.gov/document/FDA-2024-P-1130-0003 ("Minutes of Meeting with Valisure")).

[7] *See* RJN, Ex. F (Letter from Carol J. Bennett, Deputy Director Office of Regulatory Policy, Center for Drug Evaluation and Research, U.S. Food & Drug Administration to David Light, President Valisure LLC, et al., Docket No. FDA-2024-P-1130 (Aug. 28, 2024), https://www.regulations.gov/document/FDA-2024-P-1130-0004 ("FDA Interim Response to Valisure Petition")).

before testing, the methodology for the testing, or the specific results of the testing.[8] He claims that he "would not have purchased and used the Product at all or would have paid significantly less for it" had he "known that the BPO Product contained benzene and/or degrades to form benzene at the time of purchase[.]" *Id.* ¶ 8.

The Complaint asserts claims for (1) violation of the New York False Advertising Act, New York Gen. Bus. Law § 350 ("FAA"); (2) fraud/misrepresentation; and (3) negligence per se. Plaintiff seeks an order requiring THDG to pay "restitution/damages to restore all funds acquired by means of any act or practice declared by this Court" to constitute untrue or misleading advertising plus pre- and post-judgment interest, an order requiring THDG "to pay all actual and statutory damages permitted under the counts alleged[,]"and attorneys' fees. Plaintiff also purports to represent a putative class consisting of "all persons who purchased Rugby Laboratories'® branded BPO Products in the State of New York for personal, family or household use within the applicable limitations period." Compl. ¶ 92. The class specifically excludes "individuals who allege personal bodily injury resulting from the use of the BPO Products." *Id.* ¶ 93.

Plaintiff premises each of his claims on the concept that THDG's BPO Products (and all acne medications containing BPO), while "not designed to contain benzene[,]" (Compl. ¶ 45), do in fact "contain benzene and/or degrade to form benzene—a carcinogen that has been linked to leukemia and other blood cancers." Compl. ¶ 1. Without citing Valisure's testing results with respect to *THDG's* BPO Products, plaintiff extrapolates Valisure's findings and his own undisclosed independent testing results to allege that "*all lots* of [THDG's] BPO Products contain

[8] At the pre-motion conference, plaintiff's counsel was similarly vague regarding the actual testing results of his client's product. *See* Exhibit 1, Dec. 18, 2024 Hr'g Tr. at 12:2-3 ("The product—our client's product as tested is many times over [2 ppm]."); *id.* at 17:23-25 ("[M]y client's product, as alleged, contains benzene at levels which are dangerous. . .").

and/or systematically degrade to form benzene . . . at levels that vastly exceed 2 ppm." *Id.* ¶¶ 17-18 (emphasis added). According to plaintiff, THDG "knew or should have known that [its] BPO [P]roduct contained benzene, but misrepresented, omitted, and concealed this fact to consumers . . . by not including benzene on the BPO Product label or otherwise warning consumers about its presence" (*id.* ¶ 3) and failed to "disclose or warn" consumers "that the BPO Product contains benzene and/or degrades to form benzene." *Id.* ¶ 7. The Complaint also cites several other studies discussing the adverse health and safety risks associated with benzene (see Compl. ¶¶ 47-59). None of those studies relate to exposure to topical acne medications.

Plaintiff's grievances with THDG are: (1) THDG did not list benzene on its list of active or inactive ingredients on its BPO Products' labels or otherwise in advertising materials (*id.* ¶¶ 45, 76-77); (2) THDG did not warn consumers, via labels or otherwise, that the BPO ingredient in its products could degrade to form benzene (*id.*); (3) "the presence of benzene in the BPO Products" renders THDG's BPO Product "misbranded" and "adulterated" (*id.* ¶ 80); and (4) THDG should have recalled its products because "all lots" contain more than 2 ppm of benzene. *Id.* ¶¶ 17, 46. Plaintiff does not allege that the BPO Products fail to conform to the FDA's monograph establishing required labeling for acne medications containing benzoyl peroxide. The Complaint also contains no specific allegations, beyond citing Valisure's findings, that THDG could have or should have used a different ingredient than BPO in its acne medications. Nor does the Complaint allege that THDG's manufacturing process, rather than the presence of BPO itself, contaminated its BPO Products with benzene.

LEGAL STANDARD

To avoid dismissal under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its

face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This plausibility standard requires plaintiff to "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* While a court must accept a complaint's well-pleaded factual allegations as true at this stage, it must "giv[e] no effect to legal conclusions couched as factual allegations." *Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017).

Claims sounding in fraud must also meet Rule 9(b)'s heightened pleading standard. "[T]o comply with Rule 9(b), the complaint must: (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006). "To meet the requirement of Rule 9(b) a plaintiff must show the manner in which he was damaged by the implementation of a deceptive or manipulative practice or by a misrepresentation or omission." *Moran v. Kidder Peabody & Co.*, 609 F. Supp. 661, 665 (S.D.N.Y. 1985).

ARGUMENT

I. The FDCA Preempts Plaintiff's Claims.

Plaintiff's claims should be dismissed as preempted by the FDCA. Through his Complaint, plaintiff asks this Court to have THDG communicate information to the public about its BPO Products different from the information required by the FDA-approved monograph, and to find that benzoyl peroxide should no longer be recognized as a generally safe and effective ingredient in acne medications. This is the FDA's purview.

The FDCA contains an express preemption provision that prohibits states from imposing requirements on OTC drugs "that [are] different from or in addition to, or that [are] otherwise not identical with, a requirement" under the FDCA. 21 U.S.C. § 379r(a)(6). "[T]he FDCA preempts not only those state laws that are in conflict with it (*i.e.*, any law that is 'different from' the FDCA), but also *any* state law that provides for ... requirements that are not *exactly the same* as those set forth in the FDCA and its regulations." *Patora v. Vi-Jon LLC*, No. 22-cv-6678, 2023 WL 5610300, at *4 (S.D.N.Y. Aug. 30, 2023) (emphasis in original). "Preemption is thus appropriate "when a state law prohibits labeling that is *not prohibited* under federal law" and "diverges from federal law *at all*." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 376 (S.D.N.Y. 2014) (emphasis in original). "A common law rule that 'requires that manufacturers label or package their products in [a] particular way' qualifies as a requirement with respect to labeling" for purposes of preemption. *Goldstein v. Walmart, Inc.*, 637 F. Supp. 3d 95, 103 (S.D.N.Y. 2022) (citing *Bates v. Dow Agroscis*. *LLC*, 544 U.S. 431, 444 (2005)).

By taking aim at THDG's labeling and marketing of its BPO products, plaintiff seeks to impose requirements on THDG that are markedly different from the specific requirements for BPO-containing acne mediations set forth in the FDA's monograph covering these products. *See* 21 C.F.R. § 330.10, *et seq.* The FDA requires OTC drug manufacturers to list all pre-approved "active" and "inactive" ingredients on their product labels. 21 C.F.R. §§ 330.10(a)(1), (3); 330.10(a)(7)-(9). But benzene is neither, because, as plaintiff concedes, THDG's BPO Product is "not designed to contain benzene[.]" Compl. ¶ 47. Nor is benzene a "component" of the BPO Products. *See* 21 C.F.R. § 210.3 (defining a "component" as "any ingredient *intended for use* in the manufacture of a drug product") (emphasis added). Rather, it is an alleged unintended byproduct of benzoyl peroxide, for which the FDA's monograph does not require disclosure or

warnings. *See Truss v. Bayer Healthcare Pharms. Inc.*, No. 21-cv-09845, 2022 WL 16951538, at *4 (S.D.N.Y. Nov. 15, 2022) (byproduct of active ingredient's degradation is neither an active nor inactive ingredient and need not be disclosed as an ingredient under the FDCA); *Patora*, 2023 WL 5610300, at *4-*5 (S.D.N.Y. Aug. 30, 2023) (mislabeling claims based on defendant's failure to disclose potential contaminant on laxative warning labels that was not required by medication's monograph were preempted by FDCA). To require THDG to add warnings to its labels not required by the FDA's monograph would "lead precisely to the patchwork of inconsistent packaging regulations that Congress sought to prevent." *Truss*, 2022 WL 16951538, at *4.

Further, plaintiff's contention that all lots of THDG's BPO Products are unsafe because the benzoyl peroxide ingredient contains or can degrade to form benzene above 2 ppm "at a systematic rate" (*see* Compl. ¶ 20) is merely an attack on the FDA's determination that BPO acne mediations containing between 2.5-10% of benzoyl peroxide are generally recognized as safe and effective. *See* 21 C.F.R. §§ 333.301, *et seq.*; 333.350, *et seq.* The Complaint makes clear that what plaintiff wants THDG to do to avoid "any potential for benzene contamination" is to have manufactured and sold the BPO products with no benzoyl peroxide in them at all. *See* Compl. ¶ 56; *see id.* ¶¶ 31, 48. This would force THDG to depart from the monograph for BPO medications, directly contradicts the FDA's approval of benzoyl peroxide as an ingredient in acne medications, and is accordingly preempted. *See Truss*, 2022 WL 16951538, at *4; *Patora*, 2023 WL 5610300, at *4-5; *Critcher v. L'Oreal USA Inc.*, No. 18-cv-5639, 2019 WL 3066394, at *2 (S.D.N.Y. July 11, 2019), *aff'd*, 959 F.3d 31 (2d Cir. 2020); *Bowling*, 65 F. Supp. at 376; *Bischoff v. Albertsons Cos., Inc.*, 678 F. Supp. 3d 518, 524-25 (S.D.N.Y. 2023); *Goldstein.*, 637 at 111-14; *Lester v. CVS Pharmacy, Inc.*, No. 22-CV-7334, 2024 WL 1312935, at *5-7 (S.D.N.Y. Mar. 27, 2024); *Collaza*

v. Johnson & Johnson Consumer, Inc., No. 23-CV-06030, 2024 WL 3965933, at *3-5 (S.D.N.Y. Aug. 27, 2024).

The court's analysis in *Truss* is instructive. There, the plaintiffs alleged that the defendant's sunscreen product contained benzophenone, which formed from the degradation of octocrylene, one of the product's active ingredients. *Truss*, 2022 WL 16951538, at *1. As here, the plaintiffs argued that "the presence of benzophenone render[d] the Product mislabeled, misbranded, adulterated, and defective." *Id.* The injury was also the same: plaintiffs claimed that "they would have purchased the Product, or would have paid significantly less for it, had they been aware it contained benzophenone." *Id.* at *2. The court found that each of the plaintiffs' claims were expressly preempted because they arose from the defendants' alleged failure to disclose the presence of benzophenone in the product, which was not required by the FDA monograph for sunscreen, such that implementing the labeling plaintiffs sought would render the drugs misbranded. *Id.* at *4-*5. The Court should reach the same result here.

Plaintiff's conclusory allegations that THDG's BPO Products are "adulterated" and "illegal" (*see* Compl. ¶¶ 47, 54, 57) do not overcome preemption, either, for the simple reason that the Complaint does not plausibly allege that THDG's BPO Products were adulterated. A drug is adulterated if "[the] drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice." 21 U.S.C. § 351(a)(1). The Complaint never alleges that THDG did not conform to current good manufacturing practices, which resulted in benzene contamination. Instead, it is clear from the Complaint that plaintiff's underlying theory is that *all of THDG's BPO products* contain or will degrade to form unsafe levels of benzene. *See* Compl. ¶¶ 17, 57. This is not an adulteration theory. It is a disagreement with the presence of

benzoyl peroxide in the product, an approved active ingredient for BPO acne medications. *See* Valisure Citizen Petition at p. 8 ("the specific problem with benzene in benzoyl peroxide products *does not appear to be a contamination issue* from a specific ingredient, but instead the *inherent instability* of the benzoyl peroxide molecule that breaks down and forms benzene.") (emphasis added). *See also In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 20-MD-2924, 2023 WL 2756409 (S.D. Fla. July 26, 2023) (explaining that plaintiff's adulteration theories were not viable where theories were based on premise that drug was unsafe and worthless because of active ingredient that allegedly degraded to form carcinogen and thus "*self*-adulterate[d]") (emphasis added).

Plaintiff is simply second guessing the FDA's determination that acne medication containing 2.5-10% BPO is generally safe and effective. Plaintiff asserts this despite his concession that it was "well-known" in the scientific community for decades that BPO can degrade to form benzene. *See* Compl. ¶¶ 62-70. The FDA certainly took this well-known fact into account in issuing its monograph. Therefore, plaintiff's claims are preempted because the relief would impose obligations on THDG that are "in addition to" or "different" from those prescribed by the FDA in its monograph governing BPO acne medication products.

II. The FDA Has Primary Jurisdiction.

If the Court declines to dismiss any of plaintiff's claims as preempted, it should dismiss or stay the case because the FDA has primary jurisdiction over all issues presented by this suit.

The primary jurisdiction doctrine permits courts to exercise discretion to dismiss or stay proceedings and is "appropriate 'whenever enforcement of the claim requires the resolution of which, under a regulatory scheme, have been placed within the special competence of [the] administrative body.'" *Ellis v. Trib. Television Co.*, 443 F.3d 71, 81 (2d. Cir. 2006) (quoting *United*

States v. W. Pac. R.R. Co., 352 U.S. 59, 64 (1956)). In determining whether to dismiss a case based on primary jurisdiction, courts in the Second Circuit consider whether: (1) "the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise"; (2) "the question at issue is particularly within the agency's discretion"; (3) "there exists a substantial danger of inconsistent rulings"; and (4) "a prior application to the agency has been made." *Id.* at 82–83 (citation omitted). *See In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 697 (S.D.N.Y. 2016) (staying deceptive practices action pending FDA's rulemaking process); *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 326 (S.D.N.Y. 2017).

The Court here should defer to the FDA. The FDA has the primary jurisdiction to determine whether further action is needed with respect to THDG's and other manufacturers' BPO Products through the Citizen Petition process already initiated by Valisure. The decision whether to change the monograph for BPO acne medications is within the FDA's jurisdiction, expertise, and discretion. *See* 21 U.S.C. § 330.10. This is underscored by Congress's clear directive for national uniformity for ingredients and labeling of nonprescription drugs. 21 U.S.C. § 379r. Importantly, the FDA already has a mechanism through which benzoyl peroxide's status as a GRAS/E ingredient can be challenged—the Citizen Petition process allows any interested person to petition for the amendment or repeal of an OTC drug's monograph. *See* 21 C.F.R. § 10.30. Valisure *has already initiated* this process by filing a Citizen Petition, and the FDA has *already acknowledged* that it is taking Valisure's concerns under consideration. *See* Compl. ¶¶ 37-41; RJN Exs. D-F. The FDA's active consideration of the issues in plaintiff's complaint increases the risk of inconsistent rulings should the Court rule on the merits. All four factors thus favor a dismissal or stay pending FDA's consideration of these issues.

III. Plaintiff Fails to State a Claim Under N.Y. GBL § 350.

Plaintiff's claims also fail as a matter of pleading. N.Y. GBL § 350 prohibits "[f]alse advertising in the conduct of any business, trade or commerce." To state a claim under § 350, a plaintiff must plead that the defendant engaged in false advertising that was materially misleading to reasonable consumers. *See Hardy v. Olé Mexican Foods, Inc.*, No. 22-1805, 2023 WL 3577867, at *2 (2d Cir. May 22, 2023). Plaintiff has failed to do so here.

A. Plaintiff has not alleged any actionable false or misleading representations.

Plaintiff has not stated an actionable affirmative misrepresentation because he has not alleged (1) a specific, non-generalized statement by THDG in its labeling or advertising (2) that is plausibly false or misleading. *See Harris v. Pfizer Inc.*, 586 F. Supp. 3d 231, 243-44 (S.D.N.Y. 2022); *Frei v. Taro Pharms. USA, Inc*., 443 F. Supp. 3d 456, 469-70 (S.D.N.Y. 2020).

When a plaintiff rests a false advertising claim on an affirmative or implied misrepresentation, he must point to a specific statement or representation that made the advertisement misleading. *See, e.g.*, *Harris*, 586 F. Supp. 3d at 243-44. The only affirmative misrepresentations alleged in the Complaint are that THDG's "BPO Products were of merchantable quality, safe to use as prescribed, complied with federal and state law, and did not contain carcinogens or other impurities such as benzene." Compl. ¶ 62; *see also id.* ¶ 8 (alleging that plaintiff read the product's "accompanying labels and disclosures, and understood them as representations and warranties…that the BPO Product was properly manufactured, free from defects, safe for its intended use, and not adulterated or misbranded."). The Complaint does not point to one concrete example of such misrepresentations or explain why any advertisements were misleading, including on the BPO Products' labeling.

These generalized allegations, absent a specific statement identified in THDG's advertising, cannot support an actionable false or misleading advertisement. *See Harris*, 586 F. Supp. 3d at 243-44 ("A plaintiff does not have a claim under the GBL just because she comes away from an advertisement with an incorrect impression. That impression must be reasonably traceable to a misleading statement from the defendant."); *Woods v. Maytag Co.*, No. 10–CV–0559, 2010 WL 4314313, at *16 (E.D.N.Y. Nov. 2, 2010) (citing *Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 100 (S.D.N.Y 1997)) ("general references to advertisements and statements will not be sufficient to allege a deceptive act or practice").

To be misleading, an affirmative or implied misrepresentation must also have some element of plausible falsity or deceptiveness. *See id.* (dismissing FAA claim where plaintiffs failed to "explain how . . .statements [were] false or misleading") "[W]here a plaintiff has 'chosen to use scientific studies . . . to raise plausible inferences' that marketing is deceptive, and 'the studies cited do not' support her claims, the plaintiff has not plausibly pleaded her claims." *Bermudez v. Colgate-Palmolive Co.*, 667 F. Supp. 3d 24, 40 (S.D.N.Y. 2023) (quoting *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 141 (E.D.N.Y. 2015)).

Here, there is no plausible inference to be drawn that THDG's "statements" constitute false or misleading misrepresentations — *i.e.*, that all of THDG's BPO Products are not actually safe as prescribed, are of unmerchantable quality, contain benzene, or do not comply with federal or state law. As discussed above, plaintiff has not plausibly alleged that THDG did not comply with federal or state requirements for acne medications containing benzoyl peroxide. *See* Section I. Nor has plaintiff plausibly alleged that THDG's "misrepresentations" regarding safety and merchantability were false or otherwise deceptive because plaintiff has not plausibly alleged that THDG's products contain unsafe levels of benzene. Plaintiff cites Valisure's findings and his own undisclosed testing

to support his allegation that THDG's BPO Products contain unacceptable and unsafe levels of benzene above 2 ppm. *See* Compl. ¶¶ 8, 17-19. But neither supports an inference of falsity.

For the Valisure findings, plaintiff makes no allegations that any batch of *THDG's* products contained more than 2 ppm of benzene when tested *before* heating the BPO Products to above-ambient temperatures. *See* Valisure Citizen Petition at p. 16-18 (listing benzene measurements). At most, the Valisure findings support an inference that *some* BPO Products *may* degrade to form benzene when exposed to heat for days at a time.

As for his own testing, plaintiff alleges no facts that would allow the Court to infer that the BPO Product tested was unsafe. The Complaint is silent on the results or conditions of the testing other than that the threadbare statements that the testing was done at room temperature and detected "excessive levels" of benzene. *See* Compl. ¶¶ 8, 19. The Complaint is also silent on why this limited testing establishes that "*all lots* of Defendant's BPO Products contain and/or or systematically degrade to form benzene." *Id.* ¶ 17 (emphasis added). "[B]are, unsubstantiated allegations about the *possibility*" that the BPO Products contain benzene "without any additional factual support from product testing" are insufficient. *Hawkins v. Coca-Cola Co.*, 654 F. Supp. 3d 290, 306 (S.D.N.Y. 2023) (emphasis in original); *see Bermudez*, 667 F. Supp. 3d at *37-41 (finding plaintiff failed to state deceptive marketing claim against charcoal toothpaste manufacturer where studies cited in support of claim that defendant's products were unsafe did not support the premise that unsafe levels of charcoal were in toothpaste). Plaintiff has thus failed to allege that any representations by THDG that its BPO Products were "safe" constitute "misrepresentations."

B. Plaintiff has not alleged any actionable omissions.

For similar reasons, plaintiff has not stated a false advertising claim premised on a misleading omission. Omissions are actionable where the "business alone possesses material

information that is relevant to the consumer and fails to provide this information" (*In re Sling Media Slingbox Advert. Litig.*, 202 F. Supp. 3d 352, 359 (S.D.N.Y. 2016)) and the consumer could not have discovered the information "without difficulty[.]" *Woods v. Maytag Co.*, 2010 WL 4314313, at *15. Here, plaintiff does not allege that THDG failed to disclose the presence of benzoyl peroxide in its BPO products. To the contrary, its presence is prominently displayed on the label. *See* Compl. ¶ 77.

As for THDG's failure to disclose the *potential* presence of benzene, it is not a plausible inference that THDG alone possessed knowledge that benzoyl peroxide can degrade to form benzene. The Complaint alleges no facts detailing *how* or *why* THDG would have uniquely known about the degradation qualities of benzoyl peroxide despite the FDA's historical and extensive testing on the subject. Indeed, plaintiff's conclusory allegation that THDG "had superior—indeed exclusive—knowledge of the material fact that benzoyl peroxide could produce benzene and/or degrade to form benzene" (Compl. ¶ 107) is contradicted by the Complaint's own allegations. The Complaint acknowledges that the potential harmful effects of benzene exposure and its propensity to degrade to form benzene are "well known" (*id*. ¶¶ 63, 72), and that Valisure and others have been claiming to have uncovered the fact that benzoyl peroxide in various products can degrade to form benzene for many years. *Id.* ¶¶ 21-36.

Because there is no allegation that THDG alone possessed the knowledge that benzoyl peroxide can or did degrade to form benzene in any of its BPO Products, plaintiff has failed to identify an actionable omission. *See Morales v. Kimberly-Clark Corp.*, No. 18-CV-7401, 2020 WL 2766050, at *6 (S.D.N.Y. May 27, 2020).

C. Plaintiff has not alleged that THDG's labeling or advertising would likely mislead a reasonable consumer.

Even if plaintiff could identify an actionable misrepresentation or omission, he has not plausibly alleged that reasonable consumers would rely on such misrepresentations or omissions.

The standard for determining whether allegedly false, misleading, and deceptive advertising is materially misleading is an objective one: whether the defendant's "allegedly deceptive [label] w[as] likely to mislead a reasonable consumer acting reasonably under the circumstances." *Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013); *see Davis v. Pur Co. (USA), Inc.*, No. 22-CV-6430L, 2023 WL 3024407, at *2 (W.D.N.Y. Apr. 20, 2023) (SS) ("Determining whether a product label is misleading is an objective test which considers the entire label in context . . . ."). This standard requires a plaintiff to "do more than plausibly allege that a label might conceivably be misunderstood by some few consumers." *Sibrian v. Cento Fine Foods, Inc.*, No. 19-CV-0974, 2020 WL 3618953, at *3 (E.D.N.Y. July 2, 2020) (SS) (quoting *Sarr v. BEF Foods, Inc.*, No. 18-cv-6409 (ARR) (RLM), 2020 WL 729883, at *3 (E.D.N.Y. Feb. 13, 2020) (SS)). To survive dismissal, a plaintiff "must plausibly allege that a significant portion of the general consuming public or of targeted customers, acting reasonably in the circumstances, could be misled." *Id.* Whether a practice is materially deceptive of misleading may be resolved "at the motion-to-dismiss stage, where the pleading does not plausibly allege that a reasonable consumer would be deceived." *Critcher v. L'Oreal USA Inc.*, No. 18-cv-5639 (JGK), 2019 WL 3066394, at *4 (S.D.N.Y. July 11, 2019) (quoting *Podpeskar v. Dannon Co., Inc.*, No. 16cv8478, 2017 WL 6001845, at *3 (S.D.N.Y. Dec. 3, 2017)).

The Complaint contains no allegations from which the Court can infer that a reasonable consumer would be misled by implied representations that THDG's BPO Products are "safe," or by the labels' omission of "benzene" or a warning that benzoyl peroxide can degrade to form

benzene. While plaintiff states as much in conclusory terms (*see* Compl. ¶¶ 4, 83-87), common sense does not support his conclusion. *See Van Orden v. Hikari Sales U.S.A., Inc.*, No. 1:22-cv-504 (MAD/DJS), 2023 WL 5336813, at *3 (N.D.N.Y. Aug. 18, 2023) ("Courts examining misleading product claims often rely on common sense observations and judicial experience."). There is no question that THDG's BPO Product lists 10% benzoyl peroxide as an active ingredient (*see* Compl. ¶ 77), and according to plaintiff, it has been well-known for years that BPO can degrade to form benzene when exposed to heat over time. *See id.* ¶¶ 63-72.

As discussed above, THDG's "omission" of a warning that the benzoyl peroxide in its product could degrade to form benzene could thus not have plausibly been misleading to a reasonable consumer because the BPO products are clearly labeled as containing benzoyl peroxide. Benzene is a "known" potential byproduct of BPO. *See id.* ¶¶ 63-72, 77; Section III.B. Thus, any omission of a label warning consumers that the benzoyl peroxide ingredient in THDG's products might degrade to form benzene under certain conditions would not be "misleading" to a reasonable consumer. *See L'Oreal*, 2019 WL 3066394, at *4-5 (finding allegations did not "establish deception" where consumers were "generally aware" of the omission plaintiffs complained of). Plaintiff does not explain or allege facts that support an inference otherwise. *See Lee v. Mondelez Int'l, Inc.*, 637 F. Supp. 3d 116, 133-36 (S.D.N.Y. 2022) (dismissing FAA claim where complaint did "not allege anything with respect to what a reasonable consumer might believe" about alleged false advertising or "allegations to support that a reasonable consumer would believe" that label was misleading, such as by citing any sources that connected alleged misleading advertising "to the understanding of the reasonable consumer") (citing cases). His FAA claim should thus be dismissed.

IV. Plaintiff's Fraud Claim Does Not Satisfy Rule 9(b).

Plaintiff's claims do not meet Rule 9(B)'s standard to state a fraud claim. Plaintiff does not allege any facts to substantiate the who, what, when, where, and how of any alleged misrepresentation, omission, or other fraudulent act. Nor does he plead facts that would support an inference of fraudulent intent.

Under the heightened pleading standard of Rule 9(b), a plaintiff must, with particularity, "'(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent.'" *Bermudez v. Colgate-Palmolive Co.*, 667 F. Supp. 3d 24, 33 (S.D.N.Y. 2023) (quoting *Olson v. Major League Baseball*, 29 F.4th 59, 71 (2d Cir. 2022)). "Rule 9(b) also requires plaintiffs to 'allege facts that give rise to a strong inference of fraudulent intent.'" *Id.* (quoting *Dwyer v. Allbirds, Inc.*, 598 F. Supp. 3d 137, 156 (S.D.N.Y. 2022)). "A claim for fraud under New York law requires a showing of 'a misrepresentation or material omission of fact which was false and known to be false by defendant, made for the purpose of inducing the other party to rely upon it, justifiable reliance of the other party on the misrepresentation, and injury.'" *Frei*, 443 F. Supp. 3d at 470. Conclusory allegations of fraud not accompanied by "specific or sufficient facts" are not enough. *Frei*, 443 F. Supp. 3d at 470-71; *Harris*, 586 F. Supp. 3d at 240-41.

As explained above, plaintiff has failed to allege any actionable misrepresentation or omission under the FAA. Therefore, he has not detailed any misrepresentation or omission with sufficient particularly to state his fraud claim, either. *See Bermudez*, 667 F. Supp. 3d at 41 ("Because the FAC does not plead a false or misleading act, . . . the fraud claims are dismissed"); *Lee v. Mondelez Int'l Inc.*, 637 F. Supp. 3d 116, 138-39 (S.D.N.Y. 2022) (plaintiff failed to allege

misrepresentation to support of fraud claim for same reason he failed to allege reasonable consumer would have been misled by failing to disclose ingredient on labeling in support of FAA claim). The Complaint states no facts about what any specific misrepresentations were, or when or where they were made. *See* Section III.A-B. This comes far from satisfying Rule 9(b).

Plaintiff has also failed to "allege facts that give rise to [the] strong inference of fraudulent intent" required to plead his fraud claim. "A strong inference of fraudulent intent requires that a plaintiff plead (1) 'facts to show that defendants had both motive and opportunity to commit fraud' or (2) 'facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" *Bermudez*, 667 F. Supp. 3d at 43. Plaintiff has done neither. The most he alleges regarding intent is that THDG "knowingly, recklessly, or at least negligently, introduced the contaminated, adulterated, and misbranded BPO Products into the U.S. market" (Compl. ¶ 82) and "knowingly and intentionally" concealed material "facts." *Id.* ¶¶ 109, 111, 113. But he alleges nothing describing THDG's motive or opportunity to commit fraud or facts that would show conscious misbehavior or recklessness. Plaintiff's allegations that THDG "knew or should have known that the BPO Product contained benzene" (*id.* ¶¶ 3, 60), "was aware of the well-known chemical processes that degrade its BPO Product into benzene" (*id.* ¶ 72), or "would have discovered" this fact had it "adequately tested its BPO Products" (*id.* ¶¶ 73, 75, 81) are not enough, either. An inference of intent cannot be drawn solely based on such conclusory and generalized allegations that a defendant "knew or should have known" that their product was unsafe. *See, e.g.*, *Harris,* 586 F. Supp. 3d at 244 (allegation that drug manufacturer knew that drug "was at risk of being contaminated" was not "sufficient to plausibly establish that [defendant] knew about any . . . contamination in the medication that plaintiffs purchased at the time they purchased it"); *Morales*, 2020 WL 2766050, at *9 (dismissing fraud claim where complaint "lack[ed] any non-conclusory

contention that plausibly establishes Defendant's intent to deceive consumers"); *Bermudez*, 667 F. Supp. 3d at 42-43; *Lee*, 537 F. Supp. 3d at 138-39; *Hawkins*, 654 F. Supp. 3d at 308-09. Thus, plaintiff's fraud claim should be dismissed as well.

V. Plaintiff's Negligence Per Se Claim Fails.

Lastly, plaintiff has not stated a claim for negligence per se premised on violations of N.Y. Education Law § 6811(9)-(11) because THDG's labeling complied with all federal and state regulations.

New York law recognizes an independent action for negligence per se in special circumstances when a plaintiff establishes (1) that he or she is among the class of people for whose particular benefit a statute has been enacted; (2) that a private right of action would promote the legislative purpose behind the statute; and (3) that creation of the right would be consistent with the overall legislative scheme. *Toretto v. Donnelley Fin. Sols., Inc.*, 583 F. Supp. 3d 570, 598 (S.D.N.Y. 2022). Even so, for a plaintiff to recover under a negligence per se theory, the defendant must also have necessarily committed a violation of the statute that proximately harmed the plaintiff. *See Frei*, 443 F. Supp. 3d at 469.

Plaintiff cannot assert a negligence per se theory here because he has failed to plausibly allege that THDG's BPO Products were mislabeled or adulterated in violation of N.Y. Education Law § 6811(9)-(11). [9] "New York Law expressly incorporate[s] the standard imposed by the FDCA" and "provides that anything that complies with federal law and regulations *per se* complies

[9] The Court need not decide whether to permit a private right of action for plaintiff here. However, to THDG's knowledge, this Court would be breaking new ground by permitting a private negligence per se statutory action under these circumstances, as it appears that New York courts have recognized negligence per se actions premised on violations of New York's misbranding and adulteration laws only when the alleged misbranding or adulteration proximately caused *physical* injury or death, as opposed to solely economic injuries. *See Ezagui v. Dow Chem. Corp.,* 598 F.2d 727, 733 (2d. Cir. 1979); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245 (E.D.N.Y. 1999); *Fagan v. Amerisource Bergen Corp*., 356 F. Supp. 2d 198 (E.D.N.Y. 2004); *Loewy v. Stuart Drug & Surgical Supply, Inc.*, No. 91 CIV 7148, 1999 WL 16656 (S.D.N.Y. Apr. 14, 1999).

with state law." *Stewart v. Riviana Foods Inc.*, No. 16-CV-6157, 2017 WL 4045952, at *10 (S.D.N.Y. Sept. 11, 2017) (quoting *Izquierdo v. Mondelez Int'l, Inc.,* No. 16-CV-04697 (CM), 2016 WL 6459832, at *4 (S.D.N.Y. Oct. 26, 2016)). New York courts have recognized negligence per se claims premised on alleged misbranding or adulteration where such claims are based on violations of the FDCA *and* New York law. *See, e.g.*, *Frei*, 443 F. Supp. 3d at 469. Indeed, New York law could *not* impose additional requirements for THDG's OTC products, under the FDCA's express preemption provision. 21 U.S.C. § 379r; *see supra* at Section I.

Here, plaintiff has not plausibly or even explicitly alleged that THDG's products are misbranded or adulterated under the FDCA. For the same reasons, plaintiff has not plausibly alleged that THDG has violated New York's statutory prohibitions on misbranding or adulteration.

As for misbranding, plaintiff's allegations that THDG's BPO Products are "misbranded" under New York law because their labels are "false or misleading" (*see* Compl. ¶ 55) cannot withstand preemption, because by complying with the FDA monograph for acne medications they are per se *not* misbranded. *See* Section I.

Plaintiff's separate allegations of "adulteration" do not save his claims. Plaintiff alleges, in conclusory fashion, that THDG's BPO Products are "adulterated" by containing benzene above 2 ppm because they "(1) consist of a filthy, putrid, and/or decomposed substance, (2) have been prepared, packed, or held under unsanitary conditions or whereby it has been contaminated with benzene and rendered injurious to health, and (3) have a purity or qualify that falls below that which it purports or is represented to possess." *Id.* ¶ 52. But these allegations are not borne out by the Complaint or plaintiff's apparent theory that "the specific problem with benzene in benzoyl peroxide products *does not appear to be a contamination issue* from a specific ingredient, but instead the *inherent instability* of the benzoyl peroxide molecule that breaks down and forms

benzene." *See* Valisure Citizen Petition at p. 8 (emphasis added). Plaintiff's theory is that "benzoyl peroxide is an active ingredient in all [THDG] BPO Products" (Compl. ¶ 15), "[a]ll of [THDG's] BPO Products are manufactured in the same manner" (*id.* ¶ 16), "[c]ollectively, all lots of [THDG's] BPO Products contain and/or or systematically degrade to form benzene" (*id.* ¶ 17), and "[t]he rates of degradation and benzene impurities in the BPO Products occur at a systematic rate." *Id.* ¶ 20. This is not an adulteration theory. *See* Section I.

Because he has not plausibly alleged any violation of the FDCA or any "parallel" New York laws prohibiting misbranding or adulteration, plaintiff's negligence per se claim for alleged violations of New York's adulteration and misbranding laws should be dismissed. *See Frei*, 443 F. Supp. 3d at 469 (dismissing negligence per se claim based on violation of N.Y. Educ. Law § 6811 (9)–(11) where plaintiffs failed to plausibly plead that defendant had manufactured or sold a misbranded or adulterated drug); *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 448 (W.D.N.Y. 2001) (dismissing negligence per se claims where defendants had not violated FDCA).

CONCLUSION

For the reasons set forth above, THDG requests that this Court grant its motion and dismiss plaintiff's causes of action for violation of the New York FAA, fraud/misrepresentation, and negligence per se with prejudice and without leave to amend. *See Bischoff*, 678 F. Supp. 3d at 528 (denying leave to amend where "problem[s] with [Plaintiff's] causes of action [were] substantive" and "better pleading will not cure [them]") (quoting *Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000)).

Dated: January 17, 2025

Respectfully submitted,

/s/ Andrew D. Kaplan

Andrew D. Kaplan (*admitted pro hac vice*)
Rachael Padgett (*admitted pro hac vice*)
CROWELL & MORING LLP
1001 Pennsylvania Avenue NW
Washington, DC 20004
akaplan@crowell.com
rpadgett@crowell.com
Telephone: (202) 624-2699
Telephone: (202) 633-3441

Counsel for Defendant The Harvard Drug Group L.L.C. d/b/a Rugby Laboratories

CERTIFICATE OF COMPLIANCE

I hereby certify that this document contains 7,523 words and complies with the word-count limitations of Local Rule 7.1(c).

/s/ Andrew D. Kaplan

CERTIFICATE OF SERVICE

I hereby certify that on this the 17th Day of January, 2025, I caused the foregoing Notice of Motion and Memorandum in Support to be electronically filed with the Clerk of Court using the CM/ECF system which will send notification of such filing to all Counsel of record.

/s/ Andrew D. Kaplan